



# House of Representatives

General Assembly

**File No. 337**

January Session, 2007

Substitute House Bill No. 7203

*House of Representatives, April 4, 2007*

The Committee on General Law reported through REP. STONE of the 9th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

## **AN ACT CONCERNING PRESCRIPTION DRUG SUBSTITUTIONS.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 20-619 of the general statutes is repealed and the  
2 following is substituted in lieu thereof (*Effective from passage*):

3 (a) For the purposes of section 20-579 and this section:

4 (1) "Brand name" means the proprietary or trade name selected by  
5 the manufacturer and placed upon a drug product, its container, label  
6 or wrapping at the time of packaging;

7 (2) "Generic name" means the established name designated in the  
8 official United States Pharmacopoeia/National Formulary, official  
9 Homeopathic Pharmacopoeia of the United States, or official United  
10 States adopted names or any supplement to any of them;

11 (3) "Therapeutically equivalent" means drug products that are  
12 approved under the provisions of the federal Food, Drug and

13   Cosmetics Act for interstate distribution and that will provide  
14   essentially the same efficacy and toxicity when administered to an  
15   individual in the same dosage regimen; and

16       (4) "Dosage form" means the physical formulation or medium in  
17   which the product is intended, manufactured and made available for  
18   use, including, but not limited to, tablets, capsules, oral solutions,  
19   aerosol, inhalers, gels, lotions, creams, ointments, transdermals and  
20   suppositories, and the particular form of any physical formulation or  
21   medium that uses a specific technology or mechanism to control,  
22   enhance or direct the release, targeting, systemic absorption, or other  
23   delivery of a dosage regimen in the body.

24       (b) Except as limited by subsections (c) and (e) of this section, unless  
25   the purchaser instructs otherwise, the pharmacist may substitute a  
26   generic drug product with the same strength, quantity, dose and  
27   dosage form as the prescribed drug product which is, in the  
28   pharmacist's professional opinion, therapeutically equivalent. When  
29   the prescribing practitioner is not reasonably available for consultation  
30   and the prescribed drug does not use a unique delivery system  
31   technology, the pharmacist may substitute an oral tablet, capsule or  
32   liquid form of the prescribed drug as long as the form dispensed has  
33   the same strength, dose and dose schedule and is therapeutically  
34   equivalent to the drug prescribed. [The] Unless instructed otherwise  
35   by the patient or a representative of the patient, the pharmacist shall  
36   inform the patient or a representative of the patient, and the  
37   practitioner of [the] a substitution, in writing, at the [earliest  
38   reasonable] time the pharmacist dispenses a substitute prescription.

39       (c) A prescribing practitioner may specify in writing or by a  
40   telephonic or other electronic communication that there shall be no  
41   substitution for the specified brand name drug product in any  
42   prescription, provided (1) in any prescription for a Medicaid, state-  
43   administered general assistance, or ConnPACE recipient, such  
44   practitioner specifies the basis on which the brand name drug product  
45   and dosage form is medically necessary in comparison to a chemically

46 equivalent generic drug product substitution, and (2) the phrase  
47 "BRAND MEDICALLY NECESSARY", shall be in the practitioner's  
48 handwriting on the prescription form or on an electronically-produced  
49 copy of the prescription form or, if the prohibition was communicated  
50 by telephonic or other electronic communication that did not  
51 reproduce the practitioner's handwriting, a statement to that effect  
52 appears on the form. The phrase "BRAND MEDICALLY NECESSARY"  
53 shall not be preprinted or stamped or initialed on the form. If the  
54 practitioner specifies by telephonic or other electronic communication  
55 that did not reproduce the practitioner's handwriting that there shall  
56 be no substitution for the specified brand name drug product in any  
57 prescription for a Medicaid, state-administered general assistance, or  
58 ConnPACE recipient, written certification in the practitioner's  
59 handwriting bearing the phrase "BRAND MEDICALLY NECESSARY"  
60 shall be sent to the dispensing pharmacy within ten days.

61 (d) Each pharmacy shall post a sign in a location easily seen by  
62 patrons at the counter where prescriptions are dispensed stating that,  
63 "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS  
64 EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY  
65 EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR  
66 UNLESS YOU DO NOT APPROVE. IF THE PHARMACY INTENDS  
67 TO SUBSTITUTE A LESS EXPENSIVE DRUG, IT SHALL PROVIDE  
68 WRITTEN NOTICE OF THE SUBSTITUTION TO YOU." The printing  
69 on the sign shall be in block letters not less than one inch in height.

70 (e) A pharmacist may substitute a drug product under subsection  
71 (b) of this section only when there will be a savings in cost passed on  
72 to the purchaser. The pharmacist shall disclose the amount of the  
73 savings at the request of the patient.

74 (f) Except as provided in subsection (g) of this section, when a  
75 pharmacist dispenses a substitute drug product as authorized by  
76 subsection (b) of this section, the pharmacist shall label the  
77 prescription container with the name of the dispensed drug product. If  
78 the dispensed drug product does not have a brand name, the

79 prescription label shall indicate the generic name of the drug product  
80 dispensed along with the name of the drug manufacturer or  
81 distributor.

82 (g) A prescription dispensed by a pharmacist shall bear upon the  
83 label the name of the drug in the container unless the prescribing  
84 practitioner writes "DO NOT LABEL", or words of similar import, on  
85 the prescription or so designates in an oral or electronic transmission  
86 of the prescription.

87 (h) Neither the failure to instruct by the purchaser as provided in  
88 subsection (b) of this section nor the fact that a sign has been posted as  
89 provided in subsection (d) of this section shall be a defense on the part  
90 of a pharmacist against a suit brought by any such purchaser.

91 (i) The commissioner, with the advice and assistance of the  
92 commission, shall adopt regulations, in accordance with chapter 54, to  
93 carry out the provisions of this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>from passage</i>	20-619

**GL**            *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either chamber thereof for any purpose:

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**OFA Fiscal Note**

**State Impact:** None

**Municipal Impact:** None

**Explanation**

This bill establishes certain requirements for private pharmacies, and has no fiscal impact.

**The Out Years**

**State Impact:** None

**Municipal Impact:** None

**OLR Bill Analysis****sHB 7203*****AN ACT CONCERNING PRESCRIPTION DRUG SUBSTITUTIONS.*****SUMMARY:**

This bill revises the notice that pharmacists must give when making a generic substitution for a prescribed drug. The law requires pharmacists to inform the patient or patient's representative of the substitution at the earliest reasonable time. The bill instead requires that (1) the notice be written and (2) given when the pharmacist dispenses the generic equivalent drug rather than at the "earliest reasonable time." Under the bill, the patient or representative may instruct the pharmacist not to provide the written notice.

It also changes the requirements for signs that pharmacies must post about generic substitution by adding the statement: "IF THE PHARMACY INTENDS TO SUBSTITUTE A LESS EXPENSIVE DRUG, IT SHALL PROVIDE WRITTEN NOTICE OF THE SUBSTITUTION TO YOU."

EFFECTIVE DATE: Upon passage

**COMMITTEE ACTION**

General Law Committee

Joint Favorable Substitute

Yea    19    Nay   0    (03/14/2007)